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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,942	12/18/2006	Pierre Weiss	P08919US00/BAS	5251
881 7590 07/22/2009 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER HANLEY, SUSAN MARIE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 07/22/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/577,942

**Applicant(s)**

WEISS ET AL.

**Examiner**

SUSAN HANLEY

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 5-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date 05/03/2006; 12/18/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I, drawn to a silanized HEC or HPMC hydrogel in the reply filed on 06/03/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/03/2009.

Claims 1-4 are present for examination.

### ***Specification***

The specification is objected to because the compound of formula (1) is not (3-glycidoxypentyl)trimethoxysilane since it has a cyclopropyl group instead of an epoxy group.

### ***Claim Rejections - 35 USC § 112/101***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 provide for the use of a silanized hydrogel, but, since the claim does not set forth any steps involved in the method/process, it is unclear what

method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claim 4 recites the limitation "hydrogen" in line 2. There is insufficient antecedent basis for this limitation in claim 1.

#### ***Enablement***

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim 4 is drawn to a hydrogel having the structure A:

(HEC or HPMC)-O-CH<sub>2</sub>-CHOH-CH<sub>2</sub>O-(CH<sub>2</sub>)<sub>3</sub>-S-Si(ONa<sup>+</sup>)<sub>3</sub>. The elected specie for the polymer is HPMC. The specification teaches that the compound is made by reacting (3-glycidoxypopyl)trimethoxysilane with HEC or HPMC to provide a silanized polymer wherein the methoxysilane groups are hydrolyzed to produce the compound of structure A. However, this is not chemically possible because the (3-glycidoxypopyl)trimethoxysilane lacks a sulfur atom in its structure. There is no disclosure of (3-glycidoxypopyl)trimethoxysilane having a S-Si bond to make the claimed compound. Therefore, the claim nor the specification is enabled for structure A.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Daculsi et al. (US 6,001,394; cited in the IDS filed 12/18/2006).

The claims are drawn to a silanized hydroxyethyl cellulose (HEC) or silanized hydroxypropylmethyl cellulose (HPMC) hydrogel which self-crosslinks as a function of pH to form a three dimensional ex vivo culture for chondrocytes. The hydrogel is obtained by reaction HEC or HPMC with an epoxidized silanolate of the structure XSi(OZ)<sub>3</sub> wherein X denotes a halogen atom, or a hydrogen atom containing an epoxy functional group, especially C<sub>2-30</sub>, and Z is selected from a hydrogen atom, an alkali metal and an alkyl group, especially C<sub>1-5</sub>.

Daculsi discloses a polymer comprising nonionic cellulose ethers comprising HEC, HPMC or hydroxyethylmethyl cellulose (HEMC) having a silanolate side chain,  $\text{O-CH}_2\text{-CHOH-CH}_2\text{O-(CH}_2\text{)}_3\text{-Si(ONa}^+\text{)}_3$ . Daculsi specifically teaches a silanized hydrogel,  $(\text{HEC-O-CH}_2\text{-CHOH-CH}_2\text{O-(CH}_2\text{)}_3\text{-Si(ONa}^+\text{)}_3$ , (col. 4, lines 1-15). The polymer is self-crosslinking as a function of pH due to the silanolate side chains (col. 4, lines 14-35), meeting instant claim 1, in part. HEC is reacted with an epoxidized silanolate of the structure  $\text{XSi(OZ)}_3$  wherein X denotes a halogen atom, or a hydrogen atom containing an epoxy functional groups, especially  $\text{C}_{2-30}$ , and Z is selected from a hydrogen atom, an alkali metal and an alkyl group, especially  $\text{C}_{1-5}$  (instant claim 2). Daculsi specifically teaches the silanolate precursor (3-glycidoxypropyl)trimethoxysilane (col. 3, lines 55-67). The instantly elected specie polymer is HPMC. Daculsi anticipates a silanized HPMC polymer,  $\text{HPMC-O-CH}_2\text{-CHOH-CH}_2\text{O-(CH}_2\text{)}_3\text{-Si(ONa}^+\text{)}_3$ , because Daculsi discloses a small (three member) well-defined genus of nonionic cellulose ethers that are closely structurally related. Hence, the claimed HPMC specie is part of a well-defined genus which places the claimed specie in the public as in *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978) (prior art genus encompassing claimed species which disclosed preference for lower alkyl secondary amines and properties possessed by the claimed compound constituted description of claimed compound for purposes of 35 U.S.C. 102(b)).

Claim 1 recites that the hydrogel is used for three-dimensional ex vivo culture of chondrocytes. This is an intended use that does not carry patentable weight. A recitation of the intended use of the claimed invention must result in a structural

difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daculsi (US 6,001,394; cited in the IDS filed 12/18/2006).

The disclosure by Daculsi is discussed supra.

Daculsi does not teach that the HPMC carries silanolate groups of side group, alkali metal or ammonium silanolate precursor in the range of from 0.5 to 5% of the total dry weight of the HPMC polymer.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to choose appropriate limitations on the ratio between the silanolate precursor, (3-glycidoxypropyl)trimethoxysilane, and the HPMC polymer. One of ordinary in the art, a chemist, would be motivated to optimize said ratio in order to optimize the degree of cross-linking, and hence the viscosity of the hydrogel when the pH is favorable for self-crosslinking (below a pH of 10.5 (Daculsi, col. 4, lines 11-12). According to *In re Aller* 105 USPQ 233,

Normally, change in temperature, concentration, or both, is not patentable modification; however such changes may impart patentability to process if ranges claimed produce new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed critical ranges, and applicant has burden of proving such criticality; even though applicants modification results in great improvement and utility over the prior art, it may still not be patentable if modification within capabilities of one skilled in art: more particularly, where general conditions of claim are disclosed in prior art, it is not inventive to discover optimum or workable ranges by routine experimentation.



Optimization of cross-linking in polymers is well known in the art. An ordinary skilled artisan would naturally experiment with the optimum conditions for the ratio of the silanolate precursor and the HPMC polymer for the exploitation of success. It is apparent that the claimed process is merely different in degree and not in kind from the reference process.

Accordingly, it would have been *prima facie* obvious to one of skill in the art at the time the invention was made to optimize the ratio of the silanolate precursor and the HPMC polymer, especially in the absence of an objective showing of unexpected results.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,001,394. Although the conflicting claims are not identical, they are not patentably distinct from each other because '394 is drawn to a composition comprising a biomaterial that has an inorganic phase including hydroxyapatite and two optional components that are a beta-tricalcium phosphate or a calcium titanium phosphate and a liquid phase that is a biocompatible polymer that is a self-crosslinkable (under the effect of pH) polymer that is derived from cellulose, a nonionic cellulose ether, guar and starch. The self-linkable polymer (instant claim 1) is derived from the etherification of cellulose or a derivative thereof with a compound of formula,  $XSi(OZ)_3$  wherein X denotes a halogen atom, or a hydrogen atom containing an epoxy functional groups, especially  $C_{2-30}$ , and Z is selected from a hydrogen atom, an alkali metal and an alkyl group (instant claim 2). The specification discloses that a non-ionic cellulose ether is HEC, HPMC or HEMC (col. 3, lines 42-43), instant claim 1.

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure. The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be

examined." MPEP 804.

The term "comprising" is open language. Hence, the prior art composition can contain additional elements (e.g., hydroxyapatite) that are encompassed by, but not specifically named, by the claims.

It is noted that claim 9 of '394 does not teach the silanized polymer is a hydrogel however, this feature is inherent since the structure disclosed by '394 meets the instant structural limitations of claims 1 and 2. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner, Art Unit 1651

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